UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RAMAN K. BAKSHI, KHALED J. BARAKAT, RAVI P. NARGUND, BRENDA L. PALUCKI, ARTHUR A. PATCHETT, IYASSU SEBHAT, ZHIXIONG YE and LEONARDUS H.T. VAN DER PLOEG

Appeal No. 2005-1793
Application No. 09/990,499

HEARD: October 4, 2005

Before ELLIS, ADAMS, and GREEN, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the examiner's final rejection of claims 39-75, all the claims pending in the application. Claims 1-38 have been canceled.

Claims 39 and 74 are representative of the subject matter on appeal and read as follows:

> 39. A method of treating erectile dysfunction in a male subject which comprises administering to the subject in need thereof a therapeutically effective amount of a compound which is a human melanocortin-4 receptor (MC-4R) agonist wherein the binding of the compound to the human MC-4R is characterized by an IC_{50} less than 30 nanomolar (nM) and the binding of the compound to the human MC-1R is characterized by an IC_{50} greater than 30 nM.
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> 74. A method for the oral treatment of erectile dysfunction in a male subject which comprises the oral administration to the subject in need thereof a therapeutically effective amount of a compound which is an agonist of the human MC-4R.

The examiner refers to U.S. Patent No. 6,350,760 only in the double patenting rejection. The examiner has not relied on any references in making the rejections pursuant to 35 U.S.C. § 112.

The claims stand rejected as follows:

I. Claims 39-75 stand rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,350,760.

II. Claims 39-75 stand rejected under 35 U.S.C. § 112, first paragraph, "as failing to comply with the written description requirement." Answer, p. 4.

III. Claims 39-75 stand rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Answer, p. 5.

We reverse.

Background

Melanocortin receptors (MC-Rs) are members of the G-protein coupled receptor (GPCR) family. Specification, p. 1. To date, five MC-Rs have been identified. Id. According to the specification, several MC-Rs are expressed in the brain and are targets of peptides "involved in the control of food intake and metabolism." Id. For example, MC-4R is said to be "uniquely expressed in the brain, and its inactivation was shown to cause obesity." Id., sentence bridging pp. 1-2. The present invention, however, is directed to a method of using agonists of MC-4R to treat erectile dysfunction in a male subject. In particular, given the appellants' election of species (Paper No. 10, filed June 26, 2003), the invention is directed to a method of treating erectile dysfunction in male subjects using the compound set forth in Example 2 on page 75 of the specification.

Discussion

I. Double patenting

The examiner argues, in relevant part, that claims 39-75 are unpatentable "under the judicially created doctrine of obviousness-type double patenting" over claims 1-25 of U.S. Patent No. 6,350,760. Answer, p. 4. The examiner contends that

> [a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the patent are fully encompassed by the instant claims. Also, the compound of line 40[,] column 82[,] of the patent is the cis/trans stereoisomer of the elected species. Id.

We find the examiner's position to be untenable.

We point out that the present application is a divisional of the aforementioned patent. We further point out that the divisional was not voluntarily filed by the appellants, but rather it was filed in response to a restriction requirement (under 35 U.S.C. § 121) made by the examiner in the parent application. We point out that 35 U.S.C. § 121 states, in relevant part:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application nor any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

In other words, the third sentence of § 121 prohibits the use of a double patenting rejection in an application filed as a result of a restriction requirement made by the USPTO. Thus, because the examiner specifically, restricted out claims 39-75 from the parent application, the examiner cannot use the patent as a reference against said claims (i.e., make a double patenting rejection), unless the claims in the present application are directed to the "same invention" as the patent. Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 USPQ 837, 840 (Fed. Cir. 1986). Since the examiner has not established that the inventions set forth in claims 1-25 of the parent application are the same as the inventions set forth in claims 39-75 of the present application, the rejection is summarily reversed.

II and III. Written description and enablement

We find that the problem with both rejections set forth under the first paragraph of 35 U.S.C. §112 is basically the same. Accordingly, we address said rejections jointly.

With respect to the issue of whether the specification provides an adequate written description of the invention, the examiner argues that

> . . . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to choose a compound that is outside the scope of the instant formula (I) (see page 7). No structural characteristics of an agonist are provided nor is there any indication that applicant had possession of any such agonist other than the compounds of formula (I) which have already been patented (see the above double patenting rejection). The specification fails to disclose any particular structure for the claimed receptor agonists. Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claims fail to comply with the written description requirement [Answer, pp. 4-5].

With respect to the issue of enablement, we find that the examiner argues, inter alia, that (i) the specification fails to provide guidance on "how to choose a compound outside the scope of formula (I)" (Answer, p. 7); (ii) "[t]here is no description of the identifying characteristics for recognizing that a compound is a candidate for the instant claims" (id.); (iii) "[t]he ordinary artisan would be forced to pick compounds at random from all known and unknown compounds to test them randomly to see if they are MC-4R agonists having the other parameters that are disclosed in the claims" (id., p. 6.).

With both rejections we find that the examiner appears to have forgotten the election of species requirement she made on June 10, 2003 in Paper No. 9, and the appellants' election of "the species defined by Example 2 on page 75 of the specification"

on June 26, 2003 in Paper No. 10. We point out that after making an election of species requirement, the proper course of action is for the examiner to examine the claims only with respect to the elected species, even when the claims are directed to a genus. That is, all claims which read on the elected species are examined as if they were directed exclusively to said species. Thus, in examining claim 39, for example, the relevant issue is whether the specification provides an adequate written description and an enabling disclosure of a method of treating erectile dysfunction which comprises administering a therapeutically effective amount of the compound defined by Example 2 on page 75 of the specification, to a male subject. Once it has been determined that the elected species has been described and is enabled by the specification, the examiner can either (i) allow any pending or newly-submitted claims directed only to said species; or (ii) move on to the next elected species and begin the examination process with respect to that species. Eventually, the examiner may determine, based on the number of species found to be patentable, that the genus claims are also allowable. While we make no comment on whether the election of species requirement was appropriate, we do direct the examiner's attention to M.P.E.P. §§ 808.01(a) and 809.02(a). In any event, since the examiner has

not provided any reasons as to why the elected species is not adequately described or enabled by the specification, Rejections II and III are reversed.

REVERSED

JOAN ELLIS
Administrative Patent Judge)
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